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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,836	11/17/2000	Justin R. Fallon	BURF-P01-006	6928

28120 7590 09/10/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/10/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/715,836

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 15-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 13.                      6) ☐ Other:

## DETAILED ACTION

### *Status of the claims*

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-4, 16-28 and 30-54 been renumbered 1-52.

### *Election/Restrictions*

2. Applicant's election with traverse of Group I in Paper No. 16 is acknowledged. The traversal is on the ground(s) that claims of Groups III and V are directed to a mechanism, which is common with invention of Group I. Further, because Groups VI-XII each contain only one claim, the examination of all the Groups together would not impose a serious burden on Examiner. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups I, III and V are independent or distinct for the reasons in the previous Office action (see Paper No. 15). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed June 05, 2002 (Paper No. 15). Further, inventions of Groups VI-XII, each

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group containing one claim, represent different inventive concepts, which are independent or distinct from the inventive concept of Group I. The inventions are unrelated for the reasons of record in section 3 of Paper No. 15.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 16.

#### ***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not identify the post office address of inventor J. R. Fallon. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 and 9-14 are directed to methods employing biglycan or a protein having an amino acid sequence with 90% identity to a portion of biglycan, or 95% identity to amino acids 38-365 of SEQ ID NO: 9. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule of SEQ ID NO: 8, which encodes a protein which has the amino acid sequence of SEQ ID NO: 9. This amino acid molecule is identified as biglycan. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims encompass biglycan, or a protein having an amino acid sequence which is 90% identity to a portion of biglycan or 95% identity to amino acids 38-365 of SEQ ID NO: 9. First, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the polypeptide share some degree of structural similarity to the isolated protein of SEQ ID NO: 9. The specification only describes a protein having the amino acid sequence of SEQ ID NO: 9 and

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fails to teach or describe any other protein which lacks the amino acid sequence of SEQ ID NO: 9 and has the activities possessed by biglycan. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the protein of SEQ ID NO: 9. The specification does not provide a complete structure of those polypeptides which are biglycan or a protein having an amino acid sequence which is 90% identity to a portion of biglycan or a protein having 95% identity to amino acids 38-365 of SEQ ID NO: 9. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those proteins which are identified as biglycan or proteins having an amino acid sequence which is 90% identity to a portion of biglycan or proteins with 95% identity to amino acids 38-365 of SEQ ID NO: 9) because the specification teaches only the one embodiment of SEQ ID NO: 9. Therefore, the claims are directed subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1-6, 9 and 12-14 are vague and indefinite in so far as they employ the term "biglycan" as a limitation. This term encompasses a single molecular embodiment as well as the whole class of compounds, and without an appropriate definition or a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "biglycan". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "biglycan", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.
7. Claims 3-6 recite the limitation "biglycan" in claim 2. There is insufficient antecedent basis for this limitation in the claim because claim 2 recites "biglycan" three times; therefore, it is not clear which "biglycan" is recited in claims 3-6.
8. Claim 7 recites the limitation "portion of biglycan" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

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9. Claim 8 recite the limitation "biglycan" and the limitation "LLR" in claim 7. There is insufficient antecedent basis for this limitation in the claim.
10. Claim 13 is vague and ambiguous for recitation of "*Torpedo* DAG-125" biglycan. The claim appears to be directed to a specific polypeptide, however, without precise molecular sequence supported by a proper sequence identifier the metes and bounds of "*Torpedo* DAG-125" biglycan cannot be determined.
11. Claims 10 and 11 are indefinite for being dependent from the indefinite claim.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al. (WO 93/10808, 1993).

Claims 1-6, 9 and 12 are directed to a method for stabilizing dystrophin-associated protein complexes (DAPCs) on the surface of a cell by contacting the cell with biglycan. Ruoslahti et al. describe a method for treating a pathology characterized by an accumulation of extracellular matrix in a tissue by contacting said tissue with an agent that suppresses the extracellular matrix producing activity of TGF- $\beta$  (see the abstract and claim 1), wherein said agent is biglycan (see claim 8). By contacting the tissue with biglycan, stabilization of dystrophin-associated protein complexes (DAPCs) is achieved, absent evidence to the contrary. Thus, the disclosure of Ruoslahti et al. anticipates claims 1 and 2 of the instant specification.

Further, it is understood from the prior art and the instant specification that biglycan compounds possesses a property of being able to bind to alpha-dystroglycan, alpha-sarcoglycan



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and/or gamma-sarcoglycan, and also stimulate phosphorylation of alpha-sarcoglycan on a cell membrane (see page 5, lines 132 of the instant specification). Therefore, biglycan used in the method disclosed by Ruoslahti et al. inherently holds the same properties as biglycan used in the instant invention, absent evidence to the contrary. Accordingly, claims 3-6 are clearly anticipated by Ruoslahti et al..

According to the instant specification “[T]he biglycan may comprise glycosaminoglycan (GAG) side chains” (page 5, line 10). A person of ordinary skill in the art would reasonably believe that biglycan of Ruoslahti et al. “may comprise glycosaminoglycan (GAG) side chains” also. Therefore, disclosure of Ruoslahti et al. anticipates claim 9 of the instant invention.

Finally, claim 12 is directed to a method for stabilizing dystrophin-associated protein complexes (DAPCs) by contacting the cell with biglycan, which “is encoded by a nucleic acid which hybridizes to SEQ ID NO: 8”. One of skill in the art readily appreciates that without precise set of hybridization conditions, any nucleic acid can hybridize to a nucleic acid of SEQ ID NO: 8. Therefore, it can be concluded that method of claim 12 encompasses use of any biglycan molecule because the presence of SEQ ID number does not add any material limitation to the claim, as presented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 7, 8, 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruoslahti et al..

Claims 7, 8, 10, 11, 13 and 14 are directed to a method for stabilizing dystrophin-associated protein complexes (DAPCs) on the surface of a cell by contacting the cell with human biglycan or *Torpedo* DAG-125. Ruoslahti et al. disclose a method for treating a pathology characterized by an accumulation of extracellular matrix in a tissue by contacting said tissue with an agent that suppresses the extracellular matrix producing activity of TGF- $\beta$  (see the abstract and claim 1), wherein said agent is biglycan (see claim 8). By contacting the tissue with biglycan, stabilization of dystrophin-associated protein complexes (DAPCs) is achieved, absent

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evidence to the contrary. Ruoslahti et al. neither expressly disclose particular biglycans nor provide a specific amino acid or encoding sequences for identification of biglycans used in the disclosed method.

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to employ human biglycan in a method disclosed by Ruoslahti et al.. One of ordinary skill in the art would have been motivated to do this because of obvious reasons, for example, in order to avoid an immune reaction while practicing such method with human tissue (cells).

Moreover, at the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to employ any biglycan in a method disclosed by Ruoslahti et al., as long as the compound is identified as biglycan. One of ordinary skill in the art would have been motivated to do this because the disclosure of Ruoslahti et al. encompasses the use of biglycan without adding any limitation to its structure, source, method of purification or synthesis or derivation from a specific species.

### ***Conclusion***

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
September 6, 2002

OC

JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800